



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2014-0097]

Monsanto Co.; Determination of Nonregulated Status of Maize Genetically Engineered for Increased Ear Biomass

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that maize designated as event MON 87403, which has been genetically engineered for increased ear biomass, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Monsanto Company in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notices announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

DATES: Effective **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may read the documents referenced in this notice and the comments we received at <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0097> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday

through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents are also available on the APHIS Web site at [http://www.aphis.usda.gov/biotechnology/petitions\\_table\\_pending.shtml](http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml) under APHIS Petition Number 14-213-01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: [john.t.turner@aphis.usda.gov](mailto:john.t.turner@aphis.usda.gov). To obtain copies of the supporting documents for this petition, contact Ms. Cindy Eck at (301) 851-3892, email: [cynthia.a.eck@aphis.usda.gov](mailto:cynthia.a.eck@aphis.usda.gov).

#### SUPPLEMENTARY INFORMATION:

The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 14-213-01p) from Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of maize (*Zea mays*) designated as event MON 87403, which has been genetically engineered for increased ear biomass. The Monsanto petition states that information

collected during field trials and laboratory analyses indicates that MON 87403 maize is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process<sup>1</sup> for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice<sup>2</sup> published in the Federal Register on January 20, 2015 (80 FR 2674-2675, Docket No. APHIS-2014-0097), APHIS announced the availability of the Monsanto petition for public comment. APHIS solicited comments on the petition for 60 days ending on March 23, 2015, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

APHIS received 20 comments on the petition. Issues raised during the comment period include the contamination of conventional crop production, the potential for disruption of trade due to the presence of unwanted genetically engineered commodities in exports, the potential for negative impacts on plant fitness and the environment, and health concerns. APHIS decided, based on its review of the petition and its evaluation and analysis of the comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues. According to our public review process for such petitions (see footnote 1), APHIS is following Approach 2 where we first solicit written

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<sup>1</sup> On March 6, 2012, APHIS published in the Federal Register (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

<sup>2</sup> To view the notice, the petition, other supporting documents, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0097>.

comments from the public on a draft environmental assessment (EA) and a preliminary plant pest risk assessment (PPRA) for a 30-day comment period through the publication of a Federal Register notice. Then, after reviewing and evaluating the comments on the draft EA and the preliminary PPRA and other information, APHIS revises the preliminary PPRA as necessary and prepares a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a finding of no significant impact (FONSI) or a notice of intent to prepare an environmental impact statement). If a FONSI is reached, APHIS furnishes a response to the petitioner, either approving or denying the petition. APHIS also publishes a notice in the Federal Register announcing the regulatory status of the GE organism and the availability of APHIS' final EA, PPRA, FONSI, and our regulatory determination.

APHIS sought public comment on a draft EA and a preliminary PPRA from July 21, 2015, to August 20, 2015.<sup>3</sup> APHIS solicited comments on the draft EA, the preliminary PPRA, and whether the subject maize is likely to pose a plant pest risk. APHIS received 4 comments on the petition. One commenter supported a decision of nonregulated status for MON 87403 maize; two were opposed, and one was in support of nonregulated status but wanted APHIS to require continued oversight during the commercialization process. Issues raised during the comment period included concerns regarding general safety, potential for increased weediness, and the potential for gene flow to other corn varieties. APHIS has addressed the issues raised during the comment period and has provided responses to comments as an attachment to the FONSI.

#### National Environmental Policy Act

After reviewing and evaluating the comments received during the comment period on the draft EA and preliminary PPRA and other information, APHIS has prepared a final EA. The EA

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<sup>3</sup> 80 FR 43053-43055.

has been prepared to provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of maize designated as event MON 87403. The EA was prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a FONSI with regard to the preferred alternative identified in the EA (to make a determination of nonregulated status of maize designated as event MON 87403).

#### Determination

Based on APHIS' analysis of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that maize designated as event MON 87403 is unlikely to pose a plant pest risk and therefore are no longer subject to our regulations governing the introduction of certain GE organisms.

Copies of the signed determination document, PPRA, final EA, FONSI, and response to comments, as well as the previously published petition and supporting documents, are available as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 2<sup>nd</sup> day of December 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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